

Application No.: 09/914,544
Amendment RCE Submission Filed Under 37 CRF 1.114

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-20 (canceled)

21. (currently amended) A rapidly disintegrating tablet similar to those designed to disintegrate in the mouth on contact with saliva in less than 30 seconds, forming an easy-to-swallow suspension, and ~~based on an active substance in the form of obtained by direct compression of a dry mixture of~~ coated microcrystals or microgranules of an active substance and a mixture of excipients including at least one disintegrating agent, a soluble agent and a lubricating agent, wherein the lubricating agent is in powder form and the greater part or the totality of it is distributed on the tablet surface and its friability, is less than 1 %, whereby said tablet can be packaged by standard processes and has the required and adequate hardness to enable it to be removed with ease from the blister pack in which it is packed, by perforating the seal thereof by pushing the tablet, with a substantially reduced risk of the tablet breaking during removal.
22. (previously presented) Tablet in accordance with Claim 21, wherein its largest dimension is greater than 5 mm.
23. (previously presented) Tablet in accordance with Claim 21, wherein the lubricating agent is selected from the pharmaceutically acceptable lubricating agents which have a melting point of at least 35°C.
24. (previously presented) Tablet in accordance with Claim 21, wherein the lubricating agent is selected from the group including magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.
25. (previously presented) Tablet in accordance with Claim 21, wherein the lubricating agent is magnesium stearate.

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26. (previously presented) Tablet in accordance with claim 21, wherein the quantity of lubricating agent is in the range 0.2 to 10 parts per 1000 (weight of lubricating agent / total weight of tablet).
27. (previously presented) Tablet in accordance with one of Claim 21, wherein the lubricating agent has a particle size distribution which is less than 30 microns, such that its constituent particles adhere when it is sprayed against a surface.
28. (previously presented) Tablet in accordance with Claim 21, wherein the disintegrating agent is selected from the group including cross-linked sodium carboxymethylcellulose, known in the industry as croscarmellose, crospovidone and their mixtures.
29. (previously presented) Tablet in accordance with Claim 21, wherein the mixture of excipients may include a permeabilising agent, a solubilising agent, sweeteners, flavors and colorings.
30. (previously presented) Tablet in accordance with Claim 21, wherein it is designed to be packaged in blisters composed entirely of aluminum, which may in addition include a cover of a plastic material which is to be torn off before opening.
31. (currently amended) Process for the production of a tablet in accordance with Claim 21, wherein the process involves the following sequence of steps:
 - choosing, firstly, an active substance in the form of coated microcrystals or microgranules, and secondly, a set of excipients including a disintegrating agent, a soluble agent, and also a lubricating agent;
 - dry mixing the active substance and the excipients with the exception of the greater part or the totality of the lubricating agent;
 - feeding a quantity of this mixture necessary to form a tablet into the cavity of a compression device within which the mixture is to be compressed and onto the walls of which the necessary quantity of lubricating agent has been applied in advance;
 - compressing the mixture and ejecting the tablet formed.
32. (previously presented) Process in accordance with Claim 31, wherein the compression forces are in the range 3 kN to 50 kN.

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33. (previously presented) Tablet according to claim 21, wherein its friability is less than 0.5%.
34. (previously presented) Tablet in accordance with Claim 22, wherein its largest dimension is greater than 17 mm.
35. (previously presented) Tablet in accordance with claim 23, wherein the lubricating agent is selected from the pharmaceutically acceptable lubricating agents which have a melting point higher than 50°C.
36. (previously presented) Tablet in accordance to claim 26, wherein the quantity of lubricating agent is in the range 3 to 6 parts per 1000 (weight of lubricating agent / total weight of tablet).
37. (previously presented) Tablet in accordance with claim 27, wherein the lubricating agent has a particle size distribution less than 10 microns.
38. (previously presented) Process in accordance with Claim 32, wherein the compression forces are in the range 4 kN to 40 kN.
39. (previously presented) Process in accordance with Claim 38, wherein the compression forces are in the range 5 kN to 25 kN.